

MAR 9 - 2005

510(k) Summary of Safety & Effectiveness

Submitter	Vanguard Medical Concepts, Inc. 5307 Great Oak Drive Lakeland, FL 33815
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Contact	Heather Crawford, RAC Director, Regulatory Affairs (863) 683-8680 (voice) (863) 683-8703 (facsimile) hcrawford@safe-reuse.com
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Date	July 29, 2004
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Device	<ul style="list-style-type: none">• Trade Names: Vanguard Reprocessed Diagnostic Electrophysiology (EP) Catheters• Common Name: Electrode Recording Catheter, Diagnostic Electrophysiology (EP) Catheter• Classification: 21 CFR 870.1220 – Class II – Catheter, Electrode Recording, or Probe, Electrode Recording• Product Code NLH
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Predicate Devices	<ul style="list-style-type: none">• St. Jude Medical, Daig Division, Livewire™ Steerable Diagnostic Catheters (K022380)
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Indications for Use	This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.
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510(k) Summary of Safety & Effectiveness, Continued

Contra- indications

- Patients with active systemic infection.
- Patients with prosthetic valves.
- Retrograde approach in patients with aortic valve replacement.
- Transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle patch.
- Patients with acute factors that make the findings unrepresentative of the patient's usual state (i.e. drug toxicity, electrolyte abnormality, acute ischemia).
- Patients with underlying cardiac disease that increases risk of being unable to terminate induced arrhythmias and that have a high risk of death (i.e. unstable angina, acute myocardial infarction, hemodynamic instability).
- Diagnostic EP catheters are not intended for electrical ablation.

Device Description

Vanguard reprocessed Livewire diagnostic electrophysiology catheters are constructed of a hollow polymer shaft 5 – 7 French in diameter and 95 to 115 cm in length that terminates with a hand piece. Various configurations of distal platinum alloy electrodes are wired to a proximal connector for bi-directional transmission of electrical signals (pacing and recording). The hand piece is attached to an interconnecting cable that interfaces with various standard types of sensing, recording, stimulation and pacing equipment. The catheters are available with various steerable distal curves for remote manipulation of the distal tip segment that facilitates precise positioning of the electrode array. The catheters are also available in a variety of electrode configurations that are selected by the clinician based on preference and/or indication.

The shaft polymer is manufactured with additives (barium sulfate) that enhance the catheter's radiopacity to enable positioning under fluoroscopic guidance. No lumens of the catheters reprocessed by Vanguard are open to the patient bloodstream.

Vanguard collects previously used diagnostic EP catheters from healthcare facilities, and cleans, inspects, tests, applies a unique serial number, packages, labels, and sterilizes each device for return to a healthcare facility for an additional clinical use.

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510(k) Summary of Safety & Effectiveness, Continued

Technological Characteristics	Vanguard Reprocessed Diagnostic EP Catheters are essentially identical to the Original Equipment Manufacturer (OEM) devices. No changes are made to the device materials or specifications and the reprocessed catheters possess identical technological characteristics.
Test Data	Cleaning, sterilization, and packaging validations, and performance and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.
Conclusion	Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard Reprocessed Diagnostic EP Catheters are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 9 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vanguard Medical Concepts, Inc.
c/o Ms. Heather Crawford, RAC
Director of Regulatory Affairs
5307 Great Oak Drive
Lakeland, FL 33815

Re: K042074

Trade Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters
(See Enclosed List)

Regulation Number: 21 CFR 870.1200

Regulation Name: Diagnostic Intravascular Catheter

Regulatory Class: Class II

Product Code: NLH

Dated: January 12, 2005

Received: January 13, 2005

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

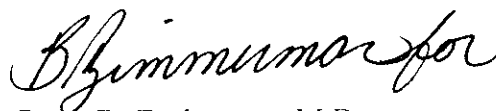
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

List of Model numbers

St. Jude Daig LiveWire™ Steerable Diagnostic Catheter - 33 Models				
401939	401933	401578	401580	401932
401940	401934	401586	401581	-
401938	401575	401587	401582	-
401941	401915	401588	401904	-
401600	401923	401583	401905	-
401603	401926	401584	401914	-
401572	401576	401585	401908	-
401606	401577	401579	401918	-

[Indications for Use

510(k) Number (if known): K042074

Device Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters

Indications for Use:

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. J. Munner
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042074